

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2013-0327; Directorate Identifier 2011-NM-161-AD]

RIN 2120-AA64

**Airworthiness Directives; The Boeing Company Airplanes****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to supersede an existing airworthiness directive (AD) that applies to all The Boeing Company Model 737-100, -200, -200C, -300, -400, and -500 series airplanes. The existing AD currently requires repetitive inspections for cracking in and around the upper and lower hinge cutouts of the forward entry and forward galley service doorways, and corrective actions if necessary. Since we issued that AD, we have received multiple reports of cracks in the skin and/or bear strap at the forward galley service doorway hinge cutouts, and multiple reports of cracking under the repairs installed at the hinge cutouts. This proposed AD would reduce the inspection threshold for cracking in and around the galley service doorway hinge cutouts, add inspections of certain repaired structure at the forward entry and galley service doorway upper and lower hinge cutouts, expand the inspection area at the forward entry and galley service doorway upper and lower hinge cutouts, and remove certain airplanes from the applicability. We are proposing this AD to detect and correct such cracking, which could result in rapid decompression of the airplane.

**DATES:** We must receive comments on this proposed AD by May 31, 2013.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202-493-2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing

Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; phone: 206-544-5000, extension 1; fax: 206-766-5680; Internet: <https://www.myboeingfleet.com>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

**Examining the AD Docket**

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:**

Alan Pohl, Aerospace Engineer, Airframe Branch, ANM-120S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6450; fax: 425-917-6590; email: [Alan.Pohl@faa.gov](mailto:Alan.Pohl@faa.gov).

**SUPPLEMENTARY INFORMATION:****Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2013-0327; Directorate Identifier 2011-NM-161-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

**Discussion**

On May 9, 2008, we issued AD 2008-11-04, Amendment 39-15526 (73 FR 29421, May 21, 2008), for all The Boeing Company Model 737-100, -200, -200C, -300, -400, and -500 series airplanes.

That AD requires repetitive inspections for cracking in and around the upper and lower hinge cutouts of the forward entry and forward galley service doorways, and corrective actions if necessary. That AD resulted from multiple reports of cracks found in the skin, bearstrap, and/or frame outer chord in the hinge cutout areas of the forward entry and forward galley service doorways. We issued that AD to detect and correct cracking, which could result in rapid decompression of the airplane.

**Actions Since Existing AD (73 FR 29421, May 21, 2008) Was Issued**

Since we issued AD 2008-11-04, Amendment 39-15526 (73 FR 29421, May 21, 2008), we have received 15 reports of cracks in the skin and/or bear strap at the forward galley service doorway hinge cutouts found on airplanes that had accumulated fewer than 40,000 total flight cycles (the inspection compliance time required by the existing AD). The lowest reported total flight cycles on an airplane with a crack were 24,423; this airplane had a 0.55-inch crack in the skin and no cracks in the bear strap. We have also received four reports of cracking under the repairs installed at the hinge cutouts as specified in the structural repair manual (SRM).

**Relevant Service Information**

We reviewed Boeing Service Bulletin 737-53A1200, Revision 2, dated September 12, 2012. For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for Docket No. FAA-2013-0327.

**FAA's Determination**

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

**Proposed AD Requirements**

This proposed AD would retain all the requirements of AD 2008-11-04, Amendment 39-15526 (73 FR 29421, May 21, 2008), and would reduce the inspection threshold for cracking in and around the galley service doorway hinge cutouts, add inspections of certain repaired structure at the forward entry and galley service doorway upper and lower hinge cutouts, expand the inspection area at the forward entry and galley service doorway upper and lower hinge cutouts, and remove certain airplanes from the applicability.

The phrase "related investigative actions" might be used in this proposed

AD. “Related investigative actions” are follow-on actions that (1) are related to the primary action, and (2) are actions that further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

In addition, the phrase “corrective actions” might be used in this proposed AD. “Corrective actions” are actions that correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

**Change to Existing AD (73 FR 29421, May 21, 2008)**

This proposed AD would retain all the requirements of AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008). Since AD 2008–11–04 was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this proposed AD, as listed in the following table:

**REVISED PARAGRAPH IDENTIFIERS**

Requirement in AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008)	Corresponding requirement in this proposed AD
paragraph (f)	paragraph (g)
paragraph (g)	paragraph (h)(1)
paragraph (h)	paragraph (h)(2)

We have revised paragraph (i) of AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008) (paragraph (i) of this proposed AD), by removing reference to Boeing 737–100/–200 SRM 53–30–1, Figures 20, 21, 31, or 32; and Boeing 737–300/–400/–500 SRM 53–10–01, Repair 5, 6, or 8. Instead, we have added Note 1 to paragraph (i) of this proposed AD to specify that guidance on repairs may be found in Boeing 737–100/–200 SRM 53–30–1, Figure 20, 21, 31, or 32; or Boeing 737–300/–400/–500 SRM 53–10–01, Repair 5, 6, or 8; as applicable.

**Differences Between the Proposed AD and the Service Information**

Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012, specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

**Costs of Compliance**

We estimate that this proposed AD affects 547 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections [retained actions from AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008)].	Up to 73 work-hours × \$85 per hour = \$6,205 per inspection cycle.	\$0	Up to \$6,205 per inspection cycle.	Up to \$3,394,135 per inspection cycle.
Inspection [new proposed action].	Up to 34 work-hours × \$85 per hour = \$2,890 per inspection cycle.	\$0	Up to \$2,890 per inspection cycle.	Up to \$1,580,830 per inspection cycle.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

**Authority for This Rulemaking**

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

**Regulatory Findings**

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

**The Proposed Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

**PART 39—AIRWORTHINESS DIRECTIVES**

- 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

- 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008), and adding the following new AD:

**THE BOEING COMPANY:** Docket No. FAA–2013–0327; Directorate Identifier 2011–NM–161–AD.

**(a) Comments Due Date**

The FAA must receive comments on this AD action by May 31, 2013.

**(b) Affected ADs**

This AD supersedes AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008).

**(c) Applicability**

This AD applies to The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, certificated in any category, as identified in Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012.

**(d) Subject**

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 53, Fuselage.

**(e) Unsafe Condition**

This AD was prompted by multiple reports of cracks in the skin and/or bear strap at the forward galley service doorway hinge cutouts, and multiple reports of cracking under the repairs installed at the hinge cutouts. We are issuing this AD to detect and correct such cracking, which could result in rapid decompression of the airplane.

**(f) Compliance**

Comply with this AD within the compliance times specified, unless already done.

**(g) Retained Repetitive Inspections**

This paragraph restates the requirements of paragraph (f) of AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008). Except as provided by paragraph (h)(1) of this AD, at the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1200, dated April 13, 2006, do external detailed, low frequency eddy current (LFEC), high frequency eddy current (HFEC), and HFEC rotary probe inspections, as applicable, for cracks in and around the upper and lower hinge cutouts of the forward entry and forward galley service doorways, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1200, dated April 13, 2006, except as provided by paragraphs (h)(2) and (i) of this AD. Do not exceed the applicable repetitive interval for the previous inspection, as specified in Boeing Alert Service Bulletin 737–53A1200, dated April 13, 2006, as Option A or Option B. Repair any crack before further flight using a method approved in accordance with the procedures specified in paragraph (o) of this AD. Accomplishment of the actions required by paragraph (j) of this AD terminates the requirements of this paragraph.

**(h) Retained Exceptions to Service Bulletin Specifications**

This paragraph restates the requirements of paragraphs (g) and (h) of AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008).

(1) Where Boeing Alert Service Bulletin 737–53A1200, dated April 13, 2006, specifies a compliance time after the release date of that service bulletin, this AD requires

compliance within the specified compliance time after June 25, 2008 (the effective date of AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008)).

(2) Although Boeing Alert Service Bulletin 737–53A1200, dated April 13, 2006, specifies contacting Boeing for information about installing an optional preventive modification that would terminate the repetitive inspections specified in paragraph (g) of this AD, this AD requires that any terminating action be done by using a method approved in accordance with the procedures specified in paragraph (o) of this AD.

**(i) Retained Optional Terminating Action**

This paragraph restates the optional terminating action specified paragraph (i) of AD 2008–11–04, Amendment 39–15526 (73 FR 29421, May 21, 2008), with revised method of compliance language. The inspections specified in paragraph (g) of this AD may be terminated at areas repaired using a method approved in accordance with the procedures specified in paragraph (o) of this AD.

**Note 1 to paragraph (i) of this AD:** Guidance on repairs can be found in Boeing 737–100/–200 SRM 53–30–1, Figure 20, 21, 31, or 32; or Boeing 737–300/–400/–500 SRM 53–10–01, Repair 5, 6, or 8; as applicable.

**(j) New Repetitive Inspections and Repair**

Except as required by paragraph (l)(1) of this AD, at the applicable times specified in Paragraph 1.E., “Compliance,” of Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012: Do an external and internal detailed inspection, HFEC inspection, and HFEC hole probe inspection, at the forward entry and galley service doorway upper and lower hinge cutouts for cracking in the skin, bonded doubler, bearstrap, and frame outer chord, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012, except as required by paragraph (m) of this AD. Options provided in Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012, for accomplishing the inspections are acceptable for compliance with the corresponding requirements of this paragraph. Repeat the applicable inspections thereafter at the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012. If any crack is found, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (o) of this AD. Accomplishment of the initial inspections terminates the requirements of paragraph (g) of this AD.

**(k) New Actions for Airplanes With Certain Repairs Installed**

(1) For airplanes with any SRM repair specified in paragraphs (k)(1)(i) though (k)(1)(vii) of this AD installed, at the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012: Do an external and internal detailed inspection, HFEC inspection, and LFEC

inspection, at the forward entry and galley service doorway upper and lower hinge cutouts for cracking in the skin, bearstrap, and frame outer chord, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012, except as required by paragraph (l)(2) of this AD. Repeat the inspection thereafter at the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012. If any crack is found, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (o) of this AD.

(i) Repair specified in Boeing 737–100/–200 SRM 53–30–03, Figure 21.

(ii) Repair specified in Boeing 737–100/200 SRM 53–30–03, Figure 31.

(iii) Repair 5 specified in Boeing 737–300 SRM 53–10–01; Repair 5 specified in Boeing 737–400 SRM 53–10–01; or Repair 5 specified in Boeing 737–500 SRM 53–10–01; installed at the upper or lower hinge cutout.

(iv) Repair specified in Boeing 737–100/200 SRM 53–30–03, Figure 20.

(v) Repair 6 specified in Boeing 737–300 SRM 53–10–01; Repair 6 specified in Boeing 737–400 SRM 53–10–01; or Repair 6 specified in Boeing 737–500 SRM 53–10–01.

(vi) Repair 8 specified in Boeing 737–300 SRM 53–10–01; Repair 8 specified in Boeing 737–400 SRM 53–10–01; or Repair 8 specified in Boeing 737–500 SRM 53–10–01.

(vii) Repair specified in Boeing 737–100/200 SRM 53–30–03, Figure 32.

(2) For airplanes with any repair installed at the forward entry doorway or forward galley doorway, upper or lower hinge cutout, that does not meet the conditions specified in paragraph 3.A.10. of the Accomplishment Instructions of Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012: Except as required by paragraph (l) of this AD, at the applicable times specified in paragraph 1.E., “Compliance,” of Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012, contact the Manager, Seattle ACO, FAA, for instructions using the procedures specified in paragraph (o) of this AD and do the actions required by the FAA.

**(l) New Exception to Service Bulletin Specifications**

(1) Where Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012, specifies a compliance time after the issue date of Boeing Service Bulletin 737–53A1200, Revision 1, dated July 7, 2011, this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where Boeing Service Bulletin 737–53A1200, Revision 2, dated September 12, 2012, specifies to contact Boeing for further instructions, this AD requires contacting the Manager, Seattle Aircraft Certification Office (ACO), FAA, for instructions and doing the actions required by the FAA, using the procedures specified in paragraph (o) of this AD

**(m) Exception for Group 5 Airplanes**

For Group 5 airplanes identified in Boeing Service Bulletin 737–53A1200, Revision 2,

dated September 12, 2012: Before further flight, contact the Manager, Seattle ACO, FAA, for instructions using the procedures specified in paragraph (o) of this AD and do the actions required by the FAA.

**(n) Credit for Previous Actions**

This paragraph provides credit for the actions required by paragraphs (j) and (k) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 737-53A1200, Revision 1, dated July 7, 2011, which is not incorporated by reference in this AD.

**(o) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: [9-ANM-Seattle-ACO-AMOC-Requests@faa.gov](mailto:9-ANM-Seattle-ACO-AMOC-Requests@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(4) AMOCs approved previously in accordance with paragraphs (f) and (i) of AD 2008-11-04, Amendment 39-15526 (73 FR 29421, May 21, 2008), are approved as AMOCs for the corresponding provisions of paragraphs (g) and (i) of this AD.

**(p) Related Information**

(1) For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Branch, ANM-120S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6450; fax: 425-917-6590; email: [Alan.Pohl@faa.gov](mailto:Alan.Pohl@faa.gov).

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; phone: 206-544-5000, extension 1; fax: 206-766-5680; Internet: <https://www.myboeingfleet.com>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on April 4, 2013.

**Ali Bahrami,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2013-08908 Filed 4-15-13; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 107**

**[Docket No. FDA-2013-N-0067]**

**Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements**

**AGENCY:** Food and Drug Administration.  
**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the regulations on nutrient specifications and labeling for infant formula to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula.

**DATES:** Submit either electronic or written comments on the proposed rule by July 1, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by May 16, 2013, (see the "Paperwork Reduction Act of 1995" section of this document).

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2013-N-0067, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document):

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Written Submissions*

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and Docket No. FDA-2013-N-0067 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "How Do You Submit Comments on This Rule?" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

With regard to the proposed rule: Benson M. Silverman, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 240-402-1450.

With regard to the information collection issues: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, [domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. What is the background of this proposed rule?**

Section 412(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(i)) establishes requirements for the nutrient content of infant formulas. Under section 412(i)(2) of the FD&C Act, the Secretary of Health and Human Services (the Secretary) is authorized to revise the list of required nutrients and the required level for any required nutrient, which authority has been delegated to the Commissioner of Food and Drugs (the Commissioner). The table in section 412(i) of the FD&C Act and FDA regulations, 21 CFR 107.100, specify that infant formulas must contain 29 nutrients; minimum levels for each nutrient and maximum levels for 9 of the nutrients are also specified.

At the time FDA established nutrient specifications for infant formula, selenium was not recognized as an essential nutrient and was not one of the nutrients required by statute in infant formula. As explained in detail in this document, selenium has subsequently been recognized as an essential nutrient. Therefore, we are proposing to amend the nutrient specifications for infant